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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,920	06/19/2000	Lawrence E. Samelson	NIH-05065	4586

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MEDLEN & CARROLL, LLP  
101 HOWARD STREET  
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EXAMINER
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HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/08/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/597,920

Applicant(s)

SAMELSON ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 June 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-6, 29, 33 and 37-60 is/are pending in the application.
- 4a) Of the above claim(s) 45-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-6, 29, 33 and 37-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

### DETAILED ACTION

1. Claim 4 has been amended.  
Claims 26-28, 30-32, 34-36 have been canceled.  
Claims 38-60 have been added.
2. Newly submitted claims 45-60 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 45-60 are directed to antibodies to SEQ ID NO:5 or to the polypeptide encoded by SEQ ID NO:2. SEQ ID NO:5 is encoded by SEQ ID NO:2 and SEQ ID NO:5 is a polypeptide that is patentably distinct from SEQ ID NO:4. Specifically SEQ ID NO:4 and SEQ ID NO:5 are completely different polypeptides and as such an antibody that binds to SEQ ID NO:4 would not necessarily bind to SEQ ID NO:5 or a polypeptide encoded by SEQ ID NO:2. A restriction would have been made for the above reasons if these claims were presented in the original restriction requirement.  
  
Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 45-60 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
3. Claims 4-6, 29, 33, 37, 38-44 are under examination.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action

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5. The following Office Action contains some NEW GROUNDS of rejection .

***Specification***

6. The disclosure is objected to because of the following informalities: The "Schematic A" on page 37 should be removed and placed as a separate figure/drawing and have a separate description in the "brief description of the drawings".

Appropriate correction is required.

***Rejections Withdrawn***

7. The rejection of claims 27, 28, 31, 32, 35, and 36 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

***Response to Arguments***

8. The rejection of claims 4, 6, 29, 37 under 35 U.S.C. 102(b) as being anticipated by Buday et al (The Journal of Biological Chemistry 269:9019-9023, 1994, IDS #5) and as evidenced from the specification is maintained.

The response filed 6/25/02 has been carefully considered but is deemed not to be persuasive. The response states "The Buday et al reference does not teach antibodies generated against a polypeptide comprising at least a portion of the amino

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acid sequence of SEQ ID NO:4" and "The 4G10 antibody is a generic antibody generated against phosphotyramine coupled to KLH and is specific for phosphotyrosine" (see page 10 of response). In response to these arguments, as stated in the response the antibody is specific for phosphotyrosine which is a portion of SEQ ID NO:4 as evidenced from the specification the protein is phosphorylated on a tyrosine residue and as such the antibody of Buday et al would bind SEQ ID NO:4. The antibody of Buday was generated against a phosphotyrosine residue and as such phosphotyrosine is a portion of SEQ ID NO:4. In addition, since SEQ ID NO:4 contains a phosphotyrosine, the Buday et al antibody is directed against SEQ ID NO:4.

9. The rejection of claims 4-5, 29 and 33 under 35 U.S.C. 102(e) as being anticipated by Hirth et al (U.S. Patent 5,958,959, filed 6/1/95) is maintained.

The response filed 6/25/02 has been carefully considered but is deemed not to be persuasive. The response states Hirth et al does not teach antibodies generated against a portion of the amino acid sequence of SEQ ID NO:4. In response to this argument, the antibody of Hirth et al is directed against a phosphotyrosine residue and as such because of the term "portion" which encompasses any part of an amino acid sequence or an amino acid, the art of Hirth et al reads on the claims.

***Th following are some NEW GROUNDS of rej ction***

***Claim Rejections - 35 USC § 112***

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10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 38 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody that binds a portion of SEQ ID NO:4, does not reasonably provide enablement for an antibody that binds to just any 20 amino acids of SEQ ID NO:4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claim is broadly drawn to antibodies to any portion of at least 20 amino acids of SEQ ID NO:4. The specification teaches antibodies to phosphorylated LAT (which is SEQ ID NO:4) (see page 41) and antibodies to SEQ ID NO:4.

The claims encompass an antibody to any 20 amino acids of SEQ ID NO:4. The specification does not teach the tertiary structure of SEQ ID NO:4 and while the specification enables the making of an antibody to any 20 amino acids of SEQ ID NO:4,

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one skill in the art would not know how to use such antibodies. The tertiary structure of the protein contains regions which are not exposed to the surface of the protein or are not accessible to an antibody. As such antibodies generated to such fragments would not recognize the folded protein and as such would not be useful in detection.

Therefore it would require undue experimentation to use the claimed invention.

12. Claims 39-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been added and recite "wherein SEQ ID NO:4 comprises a carboxy-terminus and an amino-terminus, wherein said portion comprises at least 20 amino acids from" either the amino-terminus or carboxy-terminus. The response filed 6/25/02 states that support for the newly added claims is found at page 5, lines 11-15 and page 19-20, lines 30-34 and 1-3. The response states that page 5 supports antibodies to "LAT fragments" and to "a polypeptide comprising at least a portion of the amino acid sequence of SEQ ID NO:4". The response states that the definition of fragment is "a polypeptide that has an amino terminal and/or carboxy-terminal deletion compared to the native protein, but where the remaining amino acid sequence is identical to the corresponding positions in the amino acid sequence deduced from a full-length cDNA sequence" and the fragments are "preferably at least 20 amino acids long".

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The response has been carefully considered but is deemed not to be persuasive.

Although the specification does support antibodies to LAT fragments and to portions of SEQ ID NO:4, there is no support for antibodies that bind to at least 20 amino acids from the amino-terminal or carboxy-terminal. The definition on page 19-20 is referring to "fragments" as those that comprise a deletion at the amino-terminal and/or the carboxy-terminal but the remaining sequence is the same as that from the amino acid sequence deduced from the cDNA. The "fragments" that remain after deletion are those defined as at least 20 amino acids long. The specification does not teach antibodies to "at least 20 amino acids of the amino-terminal or carboxy-terminal". The antibodies described as binding to "LAT fragments" bind fragments that are at least 20 amino acids long after deletion not to at least 20 amino acids at the carboxy-terminal or amino-terminal. Applicants are required to provide specific support for the limitations in the specification as originally filed or remove them from the claims.

### ***Conclusion***

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within



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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

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Larry R. Helms Ph.D.

703-306-5879



SHEELA HUFF  
PRIMARY EXAMINER